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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/455,978	12/06/1999	MAQSUDUL ALAM	201040/1020	5811

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EXAMINER

SCHNIZER, HOLLY G

ART UNIT	PAPER NUMBER
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1656

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/455,978

Applicant(s)

ALAM ET AL.

Examiner

Holly Schnizer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,11,16,48,49,51-54,66-71 and 73-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,11,48,49,51-54,66-71 and 73-82 is/are rejected.
- 7) ☒ Claim(s) 6 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1, 6, 11, 16, 48-49, 51-54, 66-71, and 73-82 are pending and have been considered in this Office Action.

Rejections Withdrawn

The rejection of Claims 1, 11, 66-68, 70, 73-76, and 81-82 under 35 U.S.C. 102(b) as being anticipated by Gong et al. (Proc. Natl. Acad. Sci. (Dec. 1998) 95: 15177-15182) is withdrawn in light of Applicants arguments.

The rejection of Claims 1, 11, 66-68, 70, 73-76, and 81-82 under 35 U.S.C. 102(b) as being anticipated by Monson et al. (Proc. Natl. Acad. Sci (1992) 89: 4280-4284) is withdrawn in light of Applicants arguments.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 11, 48-49, 51-54, 66-71, and 73-82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a

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way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that the Specification identifies residues within the heme binding domain that are conserved among globin-type proteins. Upon review of the Specification, it appears that the Specification discloses the manual alignment of the two oxygen sensors of the present invention with sperm whale myoglobin in an effort to find a minimal length of protein containing a "myoglobin signature motif" and see how many myoglobin proteins this sequence would recognize in the database. However, such a search does not define the structural characteristics of the protein that allow it to bind oxygen through its heme binding domain and change conformation to activate the signaling domain.

Applicants argue that the Specification teaches that the C-terminus of the proteins of the present Invention are highly homologous with the signaling domain of bacterial methyl-accepting chemoreceptors. Upon review of the Specification, it appears that the Specification teaches that the C-terminus of the two oxygen sensors disclosed therein are 30% identical to the C-terminus of Tsr (SEQ ID NO:79), a serine chemoreceptor. However, such a sequence alignment does not define the structural characteristics of the protein that allow it to bind oxygen through its heme binding domain and change conformation to activate the signaling domain.

As stated in the previous Office Action, the present Specification and the above arguments do not address questions such as: What characteristics of SEQ ID NO: 76 allow a protein to reversibly bind oxygen with low affinity or to be "salt-tolerant"? What

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characteristics of SEQ ID NO: 79 in the context of the whole protein allow it to respond to the heme binding domain and produce a signal (binding or phosphorylation).? The Specification is silent with regard to this information. Thus, with the Specification in hand, one of skill in the art would not be able to recognize what sequences would have heme binding activity and especially what protein sequences would have the coordinated heme binding and signaling *activity that allows it to be a biological sensor*. As Applicants have agreed (see Response, p. 7, 5th paragraph), the present Application discloses two proteins that form *a new class of heme-binding proteins*: a myoglobin-like heme binding protein which reversibly binds oxygen with low affinity, binds diatomic oxygen through the prosthetic group, and triggers a negative aerotactic response. However, Applicants have only described two species in this genus. The written description requirement may be satisfied through a disclosure of function and minimal structure when there is a well-established correlation between structure and function. However, without such correlation, the capability to recognize or understand the structure from mere recitation of function and minimal structure is highly unlikely and does not satisfy the written description requirements.

Applicants did not address the following section of the rejection. Therefore, it is repeated as stated in the previous Office Action:

The Specification does not set forth the invention in terms of distinguishing identifying characteristics that would allow one of skill in the art to recognize a sequence as being "bacterial" or from Archaea" or from "H. salinarum".

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Applicants' response (August 7, 2003) to the prior art rejections states that "bacterial" is a property of the claimed protein. However, the Specification nor the response identifies what property of the protein characterizes it as being "bacterial" or from "Archaea", or from "H. salinarum". At the time of the invention, recombinant technology was routine and proteins were routinely modified and recombinantly produced from sources different from the source of the originating protein. Thus, if a protein isolated from bacteria were changed by one amino acid, would it still be considered "bacterial"? If so, when does the protein cease to be considered "bacterial"—how much modification is allowed to maintain its identity as "bacterial"? These questions are not answered in the present Specification or the art. Thus, one of skill in the art would not know what sequences of all of the sequences that have 20% identity to SEQ ID NO:76 would be considered "bacterial" sequences or sequences from "Archaea" or from "H. salinarum". Thus, the claims do not meet the written description requirements.

Claim Objections

Claims 6 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusions

No claims are allowable. Claims 1, 11, 48-49, 51-54, and 66-71, and 73-82 are rejected. Claims 6 and 16 are objected to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday through Wednesday from 8 am to 5:30 pm.

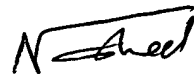
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Holly Schnizer
June 28, 2005



NASHAAT T. NASHED PHD.
PRIMARY EXAMINER